Frequently Asked Questions

NELAC Implementation

1. What version of the NELAC standards will be used by accrediting authorities to evaluate laboratories? Can the latest standard be used or must states formally adopt any changes before the new NELAC standard becomes effective? What version of the standards will the states be able to enforce?

Answer: The Ad Hoc Transition Committee has developed a policy recommendation on the effective date of standards which will be forwarded to the Board of Directors for action. This proposed policy states,

"As NELAC standards are revised or expanded, accredited laboratories and accrediting authorities must modify their operations to conform to the new standards. In order to promote nation-wide consistency in application of the standards and to minimize confusion, the following procedures shall be in effect:

- 1. If no implementation date is specified, the new or modified standard becomes effective one year from the date of adoption by the conference.
- 2. States will have up to two years to incorporate modifications to the NELAC standards into state legislation or regulations as allowed by Section 6.5(e) of the Accrediting Authority Chapter.
- 3. If a substantive modification to the NELAC standards requires more than one year for laboratories to implement, then an implementation (effective) date shall be incorporated into the new or modified standards. Standing committees are responsible for determining appropriate implementation dates.

This policy is effective until such time as this language is adopted into the NELAC standards."

The Environmental Laboratory Advisory Board in their January 14, 1999, meeting recommended that "the NELAC standards become effective and enforceable one year after adoption, and that for the first group of laboratories to be accredited under the NELAC standards, the 1999 standards be used for compliance and the related timelines for acceptance of applications be adjusted accordingly." This recommendation has been accepted by the NELAC Board of Directors.

2. How many laboratories intend to apply for NELAC accreditation in the first round? To which accrediting authorities will these laboratories apply? Will these accrediting authorities have the capacity to accommodate these laboratories in a reasonable time

frame? Will the approved accrediting authorities have the capacity to provide accreditation to out-of-state laboratories?

Answer: We do not have a firm handle on the number of laboratories that intend to apply for accreditation in the first round. We are attempting to arrive at an estimate.

Using the provision in the NELAC standards for "interim accreditation," and attempting to balance the workload among accrediting authorities should give accrediting authorities enough flexibility to handle all applicants.

With respect to accreditation of out-of-state labs, the current pool of accrediting authority applicants has indicated a capacity to accredit at least 480 out-of-state labs. Several other states may have capacity, but are not sure at this time.

3. Might there be a need for workload balancing between the accrediting authorities to accommodate all laboratories applying in the first round? If yes, how would such a system work? What would be the ground rules for such an approach?

Answer: Yes, there might be a need to balance workload among the accrediting authorities to accommodate all labs applying in the first round. The details of this approach will be established with input from all accrediting authorities approved in the first round.

4. What training on the implementation of NELAC standards will be available for laboratory assessors? When and where will this training be available?

Answer: The training of laboratory assessors on implementation of the NELAC Standards will be addressed in the Basic Training Course. The outline of this Course has already been approved by the Conference in Chapter 3. EPA is in the process of adding more detail to this outline to try to get this course closer to a format that an organization (third party or a State) could utilize to develop a Basic Training Course. Hopefully, Basic Training Courses will be available within a year. The Technical Training Courses will not be ready for implementation for probably another 2-3 years.

5. Will any of the approved accrediting authorities be using third party assessors?

Answer: One accrediting authority applicant (OR) indicated they would be using third party assessors. Three applicants (CA, CO, and TX) responded "not sure."

6. When will the first round of accrediting authority approvals be issued? When will the first round of laboratory accreditations be issued? How will approval of laboratories be phased in if it takes two or more years to inspect all laboratories?

Answer: The following timeline has been recommended by the Ad Hoc Transition Committee:

June 1999	First accrediting authorities approved
July 1999 - Sept. 1999	Laboratory applications in first round to be processed
Sept. 1999 - June 2000	Accrediting authorities review first round applications and perform initial on-site assessments of at least half of the laboratories
July 2000	First round of laboratories approved and announced, including those with interim accreditation
July 2000 - June 2001	Remainder of on-site assessments completed for first round

7. Where can one obtain the latest information on the status of accrediting authority approvals?

Answer: The latest information on the state accrediting authorities is posted on the NELAC website [www.epa.gov/ttn/nelac] and will be updated regularly at the interim and annual meetings.

8. When will EPA be able to accredit state laboratories to NELAC standards? Are there applications that state laboratories will have to submit to EPA?

Answer: EPA's NELAP office is in the process of developing a laboratory accreditation program for the state laboratories that would be in compliance with the NELAC standards. Due to the extensive efforts currently being expended in the recognition of the accrediting authorities, this program will not be operational until January 2000. Once the program is operational, the state laboratory will submit an application to EPA. In the interim, state laboratories may seek accreditation from another accrediting authority.

9. Will EPA or its regional offices be required to become recognized as accrediting authorities? Will EPA laboratories be required to be accredited in accordance with NELAC standards?

Answer: The laboratory accreditation program will be operated on a national basis. EPA in cooperation with the regional offices and NELAP will develop an accreditation program that is NELAC compliant. The Regions will take the lead on the assessments, as has been done with the recognition process for accrediting authorities. EPA is currently not requiring their laboratories to be accredited in conformance with NELAC standards. It should be noted, however, that many of the EPA laboratories intend to meet NELAC standards and become accredited. Accreditation of EPA laboratories will be conducted by NELAP.

10. What, if any, official NELAP checklists will be used to determine compliance with Chapter 5? To what extent will method specific checklists be employed? Will any checklists be part of the NELAC Chapter 3 standards?

Answer: As part of the accrediting authority recognition process, each state has been requested to use a checklist equivalent to the one posted on the NELAC website [www.epa.gov/ttn/nelac] or to describe how the assessment would address all the specific items in the checklist. In addition, a Chapter 5 checklist has been developed by the On-site Committee and is in the final stages of being put into a common format. Method specific checklists are currently not planned to be used. Checklists will be included in the Training Manual for laboratory assessors.

11. How will NELAC accommodate EPA's efforts to implement PBMS?

Answer:. The On-site and Quality Systems Committees are trying to keep the standards as flexible as possible to accommodate PBMS. As long as EPA has method specific requirements, certain constraints will be necessary within the Standard. EPA, through the Environmental Monitoring Management Council, will be providing consensus comments to the NELAC committees regarding PBMS. Those comments will be incorporated into the NELAC process and be reflected in the standards as appropriate. Laboratory assessors will need training on PBMS.

12. What can laboratories do to encourage states to become accrediting authorities?

Answer: Laboratory managers can contact state laboratory regulatory agencies to express their desire for the state agency to become a recognized accrediting authority. One way for laboratories to encourage states is for the laboratories in the state to organize a "Stakeholder's Forum." The Forum should involve an overview of NELAC for the laboratory community, presentations from the laboratory community on their desires, and a presentation from the state agency on their plans relative to NELAC. The forum should include a session for consideration of various options the state should pursue. At the conclusion of this forum, the state agency should have clear input from the lab community on a direction to pursue.